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Document Processing Desk (APPL/PETN/E-SUB/REGFEE)  
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U. S. Environmental Protection Agency  
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Attention:

Jennifer Urbanski  
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Meredith Laws

SULFOXAFLO TECHNICAL, CLOSER SC, TRANSFORM WG (AI: SULFOXAFLO)  
EPA REGISTRATION NUMBER: 62719-631, 62719-623, 62719-625  
PETITION FOR TOLERANCE – PINEAPPLE, CORN (FIELD, SWEET, AND POPCORN), SORGHUM, ALFALFA,  
CLOVER (CROP GROUP 18), AND CACAO

Dow AgroSciences is respectfully submitting an application for a tolerance petition for Sulfoxaflor Technical, Closer SC and Transform WG insecticides for Pineapple, Corn (field, sweet, and popcorn), Sorghum, Alfalfa, Clover (Crop Group 18), and Cacao.

Sulfoxaflor offers growers of these crops a new mode of action and novel chemistry. It will aid growers in resistance management because it controls insects that are resistant to other classes of insecticides. It is a good fit for IPM due to selectivity and lack of flaring of secondary pests, and it has a short soil half-life. Sulfoxaflor has demonstrated efficacy against aphids, plant bugs and mealybugs which will make it useful for growers. In particular, there is a need by growers to control aphids in corn and sorghum, and aphids and *Lygus* spp. in alfalfa. Sulfoxaflor will be used as a foliar application only in the crops listed.

In addition to these new uses, Dow AgroSciences is also proposing several other actions including: adding crops to a crop group; removing label restrictions for some crops; and review of a requested toxicology study. First, tolerances are requested for additional crops as a result of the corn residue study included with this submission, to include other cereal grains (Crop Group 15). Also, revised tolerances are proposed for milk and various meat products based on these data. See the tolerance petition and attached labels for details.

Second, Dow AgroSciences proposes removing the statement “Do not apply this product at any time between 3 days prior to bloom and petal fall” for small grain crops, such as wheat, and turfgrass. The rationale for this is that these crops are not attractive to or pollinated by bees or other insect pollinators, and petal fall is not easily determined in them.

With respect to label language for pollinators for crops included in the tolerance petition, we are proposing similar label language as on the original section 3 labels for sulfoxaflor. The previously submitted pollinator studies and risk assessment support the labeling on pollinators we have proposed here. From a benefit standpoint, sulfoxaflor offers benefits in alfalfa by replacing more toxic chemistries that are currently used. In corn, which is self-pollinated but can attract bees that gather

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pollen, sulfoxaflor is proposed to be used at low rate, a maximum of 0.047 lb ai/ha. Similarly, sulfoxaflor replaces harsher chemistries for the control of aphids. Pineapple and cacao are not pollinated by, or particularly attractive to, honey bees.

Third, EPA HED requested a confirmatory study confirming the refractory response of the human fetal nicotinic acetylcholine receptor (nAChR) expressed in mammalian cells. The new data (Millar study enclosed) are in agreement with the primary data obtained by electrophysiology in *Xenopus* oocytes, i.e., sulfoxaflor does not cause agonism at human muscle nAChRs. Therefore, the developmental effects observed in rats (fetal abnormalities and decreased neonatal survival) occur via a MoA that could not operate in humans. The overall weight of evidence from all available studies provide overwhelming evidence that developmental effects of sulfoxaflor in rats are not relevant to humans. Included here are the Millar study and addendum and a new Human Relevance Framework document.

#### **Contents of Submission on CD**

##### **Volume No.**

Volume 1

##### **Administrative Contents**

- Transmittal document (this letter)
- General Summaries for Public Release (6 Pages)
- Complimentary Copy: Pay Gov Payment Letter
- Complimentary Copy of check sent to Processing Center
- EPA Form 8570-1, Application for Pesticide,
- EPA Form 8570-34, Certification with Respect to Citation of Data
- EPA Form 8570-35, Sulfoxaflor Technical Data Matrix – Agency Copy (25 Pages)
- EPA Form 8570-35, Sulfoxaflor Technical Data Matrix – Public File Copy (25 Pages)
- EPA Form 8570-35, Transform WG Data Matrix – Agency Copy (27 Pages)
- EPA Form 8570-35, Transform WG Data Matrix – Public File Copy (28 Pages)
- EPA Form 8570-35, Closer SC Data Matrix – Agency Copy (28 Pages)
- EPA Form 8570-35, Closer SC Data Matrix – Public File Copy (29 Pages)
- Label entitled Sulfoxaflor Technical-631 18Dec13d.doc.pdf (C1C / Sulfoxaflor Technical / Amend / 12-18-13 (4 Pages plus Registration Notes)
- Label entitled: Sulfoxaflor Technical-631 18Dec13D W-Ed.doc (C1C / Sulfoxaflor Technical / Amend with Edits / 12-18-13) (4 Pages plus Registration Notes)
- Label entitled Transform WG-625 MSTR Amend 23Dec13d.doc (C1C / Transform WG / MSTR Amend / 12-23-13) (44 Pages plus Registration Notes)
- Label entitled: Transform WG-625 MSTR Amend 23Dec13d W-Ed.doc (C1C / Transform WG / MSTR Amend / 12-23-13) (44 Pages plus Registration Notes)
- Label entitled Closer SC-623 MSTR 15Oct13d.doc (C1C / Closer SC / MSTR Amend / 01-07-14) (43 Pages plus Registration Notes)
- Label entitled: Closer SC-623 MSTR 07Jan14d.doc (C1C / Closer SC / MSTR Amend / 01-07-14) (43 Pages plus Registration Notes)
- Petition for Tolerance (1 e-copy Tolerance Petition in PDF format)
- Notice of Filing Pesticide Tolerance Petition Filing dated November 2013 (1 e-copy NOF in Word format)
- Complimentary Copy of Article from Toxicology and Applied Pharmacology entitled: An Integrated Approach for Prospectively Investigating a Mode-of-Action for rodent Liver Effects

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by Matthew J. LaBaron, et.al., available on-line April 20, 2013.

- Complimentary Copy of Article from Toxicological Sciences entitled: “Mode-of-Action Mediated by the Fetal Muscle Nicotinic Acetylcholine Receptor Resulting in Developmental Toxicity in Rats” by Reza J. Rasoulpour, et.al., published March 29, 2012.
- CD containing e-PRISM.xml – New Section 3

Volume Number	MRID No.	Contents
Volume #2 860.1000, 860.1500	49146301	Residues of XDE-208 in Non-Grass Animal Feeds from the USA Author: Schreier, T. Report Date: 30 April 2013 Study ID: 110316; ARA-11-15-01 Pages: 1-756 (1PDF Copy)
Volume #3 860.1500, 860.1520	49146302	Magnitude of the Residues of Sulfoxaflo and its Major Metabolites (X11719474 and X11721061) in or on Pineapple Raw Agricultural and Processed Commodities Follow Two Applications with GF-2032 (2012) Author: Carringer, S.J., et.al. Report Date: 18 April 2013 Study ID: 120428 Pages: 1-590 (1 PDF Copy)
Volume #4 860.1000, 860.1500, 860.1520	49146303	Magnitude of Sulfoxaflo and Metabolite Residues in Raw and Processed Commodities Following Application of GF-2032 to CACAO Author: Korpalski, S.J. Report Date: 03 October 2013 Study ID: 120437 Pages: 1-475 (1 PDF Copy)
Volume #5 860.1000, 860.1500	49146304	Magnitude of Sulfoxaflo and Metabolite Residues Following Application of GF-2372 to Sweet Corn Author: Korpalski, S.J. Report Date: 01 October 2013 Study ID: 120425 Pages: 1-383 (1 PDF Copy)
Volume #6 860.1000, 860.1500, 860.1520	49146305	Magnitude of Sulfoxaflo and Metabolite Residues in Raw and Processed Commodities Following Application of GF-2372 to Field Corn Author: Korpalski, S.J. Report Date: 27 September 2013 Study ID: 120426 Pages: 1-697 (1 PDF Copy)
Volume #7 860.1000, 860.1500	49146306	Magnitude of Sulfoxaflo and Metabolite Residues Following Application of GF-2372 to Sorghum Author: Korpalski, S.J. Report Date: 30 September 2013 Study ID: 120427 Pages: 1-376 (1 PDF Copy)

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Volume #8 OPPTS No. N/A	49146307	XDE-208: Mode Of Action Evaluation And Human Relevance Framework Analysis For XDE-208-Induced Fetal Abnormalities And Neonatal Death In Rats Author: Ellis-Hutchings, R.G., et.al    Report Date: 13-November-2013 Study ID: 100290 Pages: 1-83 (1 PDF Copy)
Volume #9 OPPTS No. N/A	49146308	XDE-208: Characterization of the Agonist Effects of XDE-208 on Mammalian Muscle Nicotinic Acetylcholine Receptors by Fluorescence- Based Intracellular Calcium Assay Author: Millar, N.S.    Report Date: 20-November-2012 Study ID: NS000108 Pages: 1-18 (1 PDF Copy)
Volume # 10 OPPTS No. N/A	49146309	Addendum to NS000108: Analysis of Responses to 1mM XDE-208 in the FLIPR Assay Author: Millar, N.S.    Report Date: 12-April-2013 Study ID: NM-2013-01 Pages: 1-4 (1 PDF Copy)

If you require additional information, please contact Ronda Brown, Registration Assistant for this product, at 317-337-4563, rrbrown2@dow.com, or Kristen Shears, Regulatory Specialist, at 317-337-4791, kshears@dow.com.

Sincerely,



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Enclosures